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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,965	01/12/2001	Matthew Thomas Heisey	106281 / 0528224	1681

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EXAMINER
CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
05/29/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/759,965	HEISEY ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08/09/2004 (Rqst to reopen appeal)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,7-9,11,12 and 43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,7-9,11,12 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *05/21/2007* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

In view of the Supplemental Appeal Brief filed on August 9, 2004, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To Avoid abandonment of the application, appellant must exercise one of the follow options:

(1) file a reply under 37 C.F.R.1.111 (if this Office action is non-final) or a reply under 37 C.F.R. 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 C.F.R. 41.31 followed by an appeal brief under 37 C.F.R. 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 C.F.R. 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

SAJ 5/22/07

S. Anna Jiang, Ph.D.
Supervisory Patent Examiner
Technology Center 1600

Claims **3, 5-6, 10, 13-42 and 44-50** were cancelled, no claims have been amended, and no new claims have been added as per the response filed August 9, 2004. A Terminal Disclaimer filed October 8, 2002 has been found acceptable and entered. No additional Information Disclosure Statements (IDSs) have been received as of the mailing date of this Office action.

Claims **1-2, 4, 7-9, 11-12 and 43** remain in the case.

Claims **1-2, 4, 7-9, 11-12 and 43** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim **1** the terms "gelatin," "cartilage," "amino sugars," and "glycosaminoglycans" are directed to a vast array of compounds only a few of which are known to have the desired beneficial effects asserted in the disclosure for the claimed compositions and related kit. The remainder of the specific compounds included within the scope of the generic terms noted are not properly described within the instant written description.

Applicant's arguments filed August 9, 2004 have been fully considered but they are not deemed to be persuasive.

Applicant argues at page 3 of the supplemental brief that "[i]t is this very high level of skill and predictability, to which the Examiner refers, that enables a practitioner skilled in the art and conveys that the present inventors did indeed have possession of the claimed invention when the present application was filed." Examiner respectfully disagrees and asserts that applicant's response as avoided the point of the rejection, namely that only part of the claimed subject matter is highly predictable but that this predictability does not extend to the generic terms "cartilage," "aminosugars [other than glucosamine]," and "glucoaminoglucans [other than chondroitin]." In light of applicant's conclusory avoidance of this issue, examiner has maintained the instant rejection.

In order to facilitate understanding of the issues in this case, examiner's response to applicant's arguments filed December 23, 2002 (appeal brief) have been repeated herein.

Applicant argues in the appeal brief at beginning at page 6 that the terms chosen include compounds with different levels of efficacy but does not admit than any of these additional undisclosed compounds lack the desired pharmaceutical effect; i.e. that the entire generic class of compounds encompassed by the noted generic terms is active. However, applicant cites no authority or factual basis for this assertion. Examiner admits on the record that glucosamine, chondroitin, methylsulfonylmethane and S-adenosyl methionine are each known individually and in mixtures to be effective agents to assist in the treatment of arthritis. However, in the absence of data to the contrary, examiner argues that the great breadth of the generic terms is excessive because applicant has failed to provide the requisite guidance for the ordinary practitioner to determine the key component part or parts required of each member of each

generic class for said member to have the claimed efficacy. Therefore, this argument is deemed to be an inadequate response and for this reason not a proper basis for withdrawal of the instant rejection.

Claims **1 and 2** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims is very large because of reliance in the claims on generic terms including "cartilage," "aminosugars," "glycosaminoglycans," and "mixtures thereof" which are directed to a vast array of different oligomeric and polymeric substances.

B. The nature of the invention is directed to beverage compositions which have utility in the treatment of joint dysfunctions including arthritis.

C. The state of the prior art is well developed as revealed by the very long lists of prior art citations provided by applicant and by examiner, but are limited in the specific exemplifications to the administration of compositions containing the specific compounds glucosamine, chondroitin, methylsulfonylmethane and S-adenosyl methionine or subsets thereof. Examiner notes Table 10-2 in the newly cited **Lehninger** reference (PTO-892 ref. **W**) which identifies the chemical contents of naturally occurring saccharides and oligosaccharides found in mammals, a disclosure which raises the question of whether compounds other than glucosamine and chondroitin are effective sources of the molecular building blocks necessary to permit the mammalian joint-related tissues to be repaired *in vivo* by the instant compositions as suggested by instant claim **43** wherein administration instructions are provided.

D. The level of one or ordinary skill is high in light of the very large number of references which provide very substantial guidance concerning how to administer nutritive and non-nutritive compositions containing glucosamine, chondroitin, methylsulfonylmethane,

cartilage and S-adenosyl methionine to effect the *in vivo* repair of mammalian joint tissues. However, the level of skill of the ordinary practitioner is very low when other members of the genus aminosugars and the genus glucosaminoglycans are substituted for glucosamine and chondroitin, respectively.

E. The level of predictability in the art is very high when glucosamine, chondroitin, methylsulfonylmethane, cartilage and S-adenosyl methionine are the active ingredients, but becomes very low when other members of the genus aminosugars and the genus glucosaminoglycans are substituted for glucosamine and chondroitin, respectively.

F. The amount of direction provided by the inventor is limited to two examples with some analysis of the prior art in support of the substantial array of molecules and extracts which are found within the carrier.

G. The existence of working examples is limited to two examples and these examples are directed only to composition preparation, and do not include any medicinal testing data.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be very low if the active ingredients are limited to glucosamine, chondroitin, methylsulfonylmethane, cartilage and S-adenosyl methionine, but becomes exceptionally high when the vast arrays of other members of the genus aminosugars and the genus glucosaminoglycans are substituted for glucosamine and chondroitin, respectively. Examiner therefore concludes that limitation of the instant claims to glucosamine and chondroitin is therefore an appropriate way to avoid a clear case of undue experimentation.

Applicant's arguments filed August 9, 2004 have been fully considered but they are not deemed to be persuasive.

Applicant argues that examiner has agreed that "predictability" in the instant case is "high" without the particular qualifying limitations included above. Examiner respectfully disagrees, noting the very small amount of exemplifying data and the complete absence of any medicinally relevant test data to permit the ordinary practitioner to extrapolate beyond the compounds (e.g. glucosamine, etc.) with well known in the art medicinal effects. Therefore, in view of applicant's failure to provide the requisite medicinally relevant test data necessary to

support the full scope of the instant claimed subject matter the above rejection has been maintained.

The following is a quotation of 35 U.S.C. §103(**a**) which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **1-2, 4, 7-9, 11-12 and 43** are rejected under 35 U.S.C. §103(**a**) as being unpatentable over **Nutramax Laboratories '816** (PTO-1449 ref. **CA**) in view of **Florio '715** (PTO-1449 ref. **BF**), **Martino '692** (PTO-1449 ref. **BM**), **Burger '919** (PTO-14549 ref. **BG**), **Murad '594** (PTO-1449 ref. **BE**), and **Herschler '878** (PTO-1449 ref. **AU**) and further in view of **applicant's own admissions, Vanderveen et al.** (PTO-892 ref. **U**) and **Swinyard et al.** (PTO-892 ref. **V**).

The instant claims are directed to beverage (liquid) compositions containing cartilage, glucosamine, chondroitin, methylsulfonylmethane, and S-adensoyl methionine and numerous additional nutritional and non-nutritional additional ingredients and carriers for the purpose of treating arthritis, and a kit for this specific purpose including written instructions for the administration/consumption of the composition to, or by, an end user in need thereof.

Nutramax Laboratories '816 (PTO-1449 ref. **CA**) discloses the administration of compositions including glucosamine, chondroitin, and optionally various vitamins and minerals (nutrients) for the treatment of arthritis in mammals.

Florio '715 (PTO-1449 ref. **BF**)discloses the administration of compositions including glucosamine, chondroitin, and optionally lipids/fatty acids in liquid form including administration instructions for the treatment of arthritis in mammals.

Marino '692 (PTO-1449 ref. **BM**) discloses the administration of compositions including cartilage, glucosamine, chondroitin, and optionally various nutrients for the treatment of arthritis in mammals.

Burger '919 (PTO-1449 ref. **BG**; also specifically cited by applicant's disclosure) discloses the administration of compositions including glucosamine, and optionally lipids/fatty acids for the treatment of arthritis in mammals.

Murad '594 (PTO-1449 ref. **BE**) discloses the administration of compositions including glucosamine, chondroitin, and optionally nutrients including vitamins and minerals for the treatment of arthritis in mammals.

Herschler '878 (PTO-1449 ref. **AU**) discloses the administration of compositions including methylsulfonylmethane, and optionally as part of a nutrient (food) for the treatment of arthritis in mammals.

Applicant's own admissions: at page 1, original lines 12-13, applicant admits that the prior art teaches the effectiveness of glucosamine and chondroitin in the the treatment of osteoarthritis (hereinafter "arthritis"). Applicant also admits in the same paragraph that numerous commercial products in this art area are readily formulated into beverage compositions immediately prior to consumption. At the top of page 2, applicant further admits that "[c]hondoprotective agents may be delivered in the form of compositions having high sugar content." Applicant also admits at page 11, last full paragraph, that methylsulfonylmethane is known in the prior art to have been administered to treat arthritis. Applicant admits at page 12, three lines from the bottom of the page, that "[s]weetening agents are commonly known in the art," and at lines 9-11 of page 12 also admits that certain naturally occurring sweeteners are well known in that art. At the top of page 14, applicant also admits that other commercially available sweeteners including "saccharin" are well known in the art.

Vanderveen et al. (PTO-892 ref. **U**) in chapter 51 of Remington's Pharmaceutical Sciences, 18th Edition, entitled "Vitamins and Other Nutrients," discloses a long list of substances normally found in food stuffs including the nutrients "glucose," "fats and oils," and "fructose."

Swinyard et al. (PTO-892 ref. **V**)in chapter 66 of Remington's Pharmaceutical Sciences, 18th Edition, entitled "Pharmaceutical Necessities," discloses numerous substances included within the instant claims including generically "flavoring agents" including "saccharin," "cherry juice," "raspberry juice," and "sucrose," "Vehicles" and "Diluting Agents" including

water, "Emulsifying and Suspending Agents," "Pharmaceutical Solvents" including "water," and "Miscellaneous Pharmaceutical Necessities" including "lactose."

Applicant's disclosure does not provide any showing of unexpected results. Therefore, applicant has merely provided directions for the admixing of active ingredients of known pharmaceutical activity (cartilage, glucosamine, chondroitin, methylsulfonylmethane, and S-adensoyl methionine) each of which has been included in one or more of the cited prior art compositions which are asserted repeatedly in the prior art to be effective in the treatment of arthritis. These pharmaceutical activities are each also admitted by applicant's own disclosure. The additional components of the claimed composition are also well known in the art and are not asserted to be anything other than carriers or pharmaceutical necessities and/or nutrients several of which are specifically listed in the cited art, and none of which are asserted by applicant to represent a critical feature for any final composition. The presence of instructions directed to the end user is also a feature known in the prior art cited above (see ref. **BF**).

In light of applicant's failure to provide any data to support an unexpected benefit from the instant claimed compositions, the instant claimed compositions, kits thereof and methods of administration thereof, are deemed to lack patentable distinction as being nothing more than a mixture of substances known in the prior art as anti-arthritis agents and therefore obvious compositions to be administered to a host in need thereof. Any additional compounds acting in concert has the carrier or excipient (e.g. sweeteners, etc., etc.) have been included in the spirit of making the resultant composition palatable and optionally nutritious as admitted by applicant's own disclosure, and as generically taught by the Vanderveen and Swinyard disclosures.

Therefore, the instant claimed compositions and kits with instructions and methods of administration would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

Applicant's arguments filed August 9, 2004 have been fully considered but they are not deemed to be persuasive.

Applicant's initial response to the instant rejection is incomplete because the response beginning at page 3 of the August 9, 2004 response fails to address the entirety of the art cited in the rejection, or the clear disclosure by art cited above of liquid compositions (e.g , **Florio**

'715) comprising compounds listed in the instant claims as active ingredients. The only basis for an allegation of patentability seems to be applicant's allegation that the claimed compositions are i) low in calorie content and ii) stable, but without any showing that these problems could not be solved by any ordinary practitioner by merely perusing the art and making a mixture of anti-arthritis-agents during the course of routine experimentation. Applicant has asserted patentability but has failed to show any unexpected results for claims directed to a composition wherein the contents represent a list of known compounds formulated into a liquid composition taught by applicant's disclosure to be a -- pharmaceutical composition -- capable of effectively treating osteoarthritis. Applicant is also reminded that compositions containing a known compound(s) is(are) not patentable if it would be obvious in the prior art to utilize a carrier with the compound: see *In re Lerner* , (CCPA 1971) 438 F2d 1008; 169 USPQ 51; and *In re Rosicky* , (CCPA 1960) 276 F 2d 656, 125 USPQ 341.

For these reasons the instant ground of rejection has been maintained.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

LECrane:lec
05/21/2007

L. E. Crane, Ph.D., Esq.
Patent Examiner
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